PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
DES01		
International application No.	International filing date (*day/month/year*)	Priority Date (*day/month/year*)
PCT/IN 2004/000399	23 December 2004 (23.12.2004)	23 December 2003 (23.12.2003)
International Patent Classification (IPC) or national classification and IPC		
IPC[8]: ***A61K 31/451*** (2006.01)		
Applicant		
SUN PHARMACEUTICAL INDUSTRIES LIMITED		

1. This international preliminary examination report has been prepared by this International Preliminary Examination Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 9 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of _____ sheets.

3. This report contains indications relating to the following items:

- I. ☒ Basis of the opinion
- II. ☒ Priority
- III. ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV. ☒ Lack of unity of invention
- V. ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI. ☒ Certain documents cited
- VII. ☒ Certain defects in the international application
- VIII. ☒ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
28. May 2005 (28.05.2005)	4 August 2006 (04.08.2006)
Name and mailing address of the IPEA/AT Austrian Patent Office Dresdner Straße 87 A-1200 Vienna Facsimile No. 1/53424/200	Authorized officer KRENN M. Telephone No. 1/53424/435

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/IN 2004/000399

I. Basis of the report

1. With regard to the **elements** of the international application:*

☒ the international application as originally filed

☐ the description:
pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____.

☐ the claims:
pages _____, as originally filed
pages _____, as amended (together with any statement) under Article 19
pages _____, filed with the demand
pages _____, filed with the letter of _____.

☐ the drawings:
pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____.

☐ the sequence listing part of the description:
pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____.

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in printed form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____.

☐ the claims, Nos. _____.

☐ the drawings, sheets/fig _____.

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

** Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as „originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).*

*** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/IN2004/000399

Box No. II Priority

1. ☒ This report has been established as if no priority had been claimed due to the failure to furnish within the prescribed time limit the requested:

   ☒ copy of the earlier application whose priority has been claimed (Rule 66.7(a))

   ☐ translation of the earlier application whose priority has been claimed (Rule 66.7(b))

2. ☐ This report has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rule 64.1). Thus for the purposes of this report, the international filing date indicated above is considered to be the relevant date.

3. Additional observations, if necessary:

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

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III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 8, 9.

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination *(specify)*:

☒ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. 8 ,9 are so unclear that no meaningful opinion could be formed *(specify)*:

Characterization of a composition by storage instructions is insufficient.

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 8, 9.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees the applicant has:

☐ restricted the claims.

☐ paid additional fees.

☐ paid additional fees under protest.

☐ neither restricted nor paid additional fees.

2. ☐ This Authority found that the requirements of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirements of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

☐ complied with.

☒ not complied with for the following reasons:

1., Oral composition containing desloratadine and an antioxidant optionally in admixture with an organic compound that provides an alkaline pH and/or and alkali metal salt (claims 1-3,10,11,15).
2., Oral composition containing desloratadine and a pharmaceutically acceptable organic compound that provides an alkaline pH optionally in admixture with an antioxidant and an alkyli metal salt (claims 1,4,5,12,13,15).
3., Oral composition containing desloratadine and an alkali mtal salt optionally in admixture with an antioxidant and an organic compound that provides an alkaline pH (claims 1,6,7,14).

As the applicant has not paid an additional fee in response to form PCT/ISA/206, the search has been restricted to claims 1-3,10,11 and 15. As a result thereof the preliminary examination report has also been established only for said claims 1-3,10,11 and 15.

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this opinion:

☐ all parts.

☒ the parts relating to claims Nos. 1-3, 10, 11, 15.

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V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	11, 15	YES
	Claims	1-3, 10	NO
Inventive step (IS)	Claims	11, 15	YES
	Claims	1-3, 10	NO
Industrial applicability (IA)	Claims	1-3, 10, 11, 15	YES
	Claims	----	NO

Citations and explanations (Rule 70.7)

US 2003/0194430 A1 refers to a multi-compartment capsule; preferably one compartment is filled with a H_1-antagonist, e.g. desloratadine and the other contains a radical scavenging, e.g. vitamin E.

US 2003/0118654 A1 discloses a liquid pharmaceutical formulation comprising at least one unpleasant tasting drug, e.g. descarboethoxyloratadine and an antioxidant.

The subject matter of US 2003/0031713 A1 is a bilayer solid composition wherein one layer contains desloratadine in admixture with at least one antioxidant.

CN 1415613 A describes a stable composition of desloratadine fumarate; said salt is obligatorily formed, if desloratadine and fumaric acid are not formulated separately.

In respect of the above cited documents an oral formulation (claims 1-3,10) containing desloratadine in admixture with up to 5 % of at least one anti-oxidant is neither new nor inventive. Claims 11 and 15 show both novelty and inventive step, because none of the cited documents mentions butylated hydroxyl toluene, optionally in admixture with meglumine, as anti-oxidant.

The priority document filed by the applicant has shown the accuracy of the claimed priority date; thus the documents CN 1552324 A, US 2003/0236236 A1 and WO 2004/080461 A2, which were published within the priority term, are now without any relevance.

Industrial applicability is given for claims 1-3, 10, 11 and 15.

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VI. Certain documents cited

1. Certain published documents (Rule 70.10)

Application No. Patent No.	Publication date *(day/month/year)*	Filing date *(day/month/year)*	Priority date (valid claim) *(day/month/year)*
WO 2004/080461 A2	23.9.2004	12.3.2004	12.3.2003, 28.10.2003, 3.11.2003, 1.12.2003
US 2003/0236236 A1	25.12.2003	22.5.2003	
CN 1552324 A	8.12.2004	28.5.2003	

2. Non-written disclosures (Rule 70.9)

Kind of non-written disclosure	Date of non-written disclosure (day/month/year)	Date of written disclosure referring to non-written disclosure (day/month/year)

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

The formulation "..a pharmaceutically acceptable organic compound that provides an alkaline pH.." (claim 1) is function-oriented and should be specified.
The use of the term "about" (claim 3) in connection with numerical ranges is not allowed.

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

The term "therapeutically effective" (claim 1) is meaningless and should be therefore deleted.